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EXAMINER	
MAIER, LEIGH C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/485,377	Applicant(s) SOMMERMEYER
Examiner Leigh Maier	Art Unit 1623

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

4)  Claim(s) 1-20 is/are pending in the application. 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-20 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### *Status of the Claims*

Claims 1-13 have been amended. Claims 14-20 have been added.

### *Specification*

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The specification is objected to because of references to claims at page 3. The claims have already been amended prior to examination, so they already differ from their original form. Typically in prosecution, claims are further amended and/or canceled, so that a reference to particular claim(s) is rendered meaningless.

The specification is further objected to for lacking a “Brief Description of the Drawing(s)” as set forth in 37 CFR 1.74.

### *Drawings*

The drawing is approved by the draftsperson.

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***Claim Objections***

Claim 12 is objected to because of the following informalities: "least" (line 2) is misspelled. Appropriate correction is required.

***Claim Rejections - 35 U.S.C. § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claim 1: The claim recites the phrase “possibly substituted” (lines 2 and 4) which indicates that the derivatives are ones having reactive sites that are able to be substituted. It is not clear if this is what Applicant intends, or rather “optionally substituted” which would indicate that the process can use unsubstituted starch or substituted starch derivatives in the hydrolysis process. The claim is thus rendered vague and indefinite.

Further regarding claim 1: The claim recites “by converting” (line 2) but it is not clear what is being converted, thus rendering the claim vague and indefinite.

Further regarding claim 1: The term “reaction stage” (line 5) is not specifically used or defined in the specification. The claim appears to be referring to the “reactor” as described at page 4, second full paragraph, but this is not clear. The claim is thus rendered vague and indefinite.

Further regarding claim 1: The claim recites “essentially free of mixing” (line 5). It is not clear if this phrase is simply meant to preclude mechanical mixing in the reactor. Otherwise, it is not clear how the reaction would proceed without mixing due to normal motion of the molecules in solution. The claim is thus rendered vague and indefinite.

Regarding claims 3 and 14: The claims recite the term “fine hydrolysis,” (lines 2 and line 1, respectively) but it is not defined in the specification, and it is not clear that it is an art-recognized term. The claim is thus rendered vague and indefinite.

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Further regarding claims 3 and 14: The terms “the main hydrolysis” and “the roughly hydrolyzed starch solution.” (bridging lines 2 and 3, and line 2, respectively) There is insufficient antecedent basis for these limitations.

It is further noted that the claims use the terms “main/rough hydrolysis” and “fine hydrolysis.” It appears that “rough hydrolysis” refers to hydrolysis that occurs relatively early in the process, and “fine hydrolysis” refers to hydrolysis that occurs at some time after the “main/rough hydrolysis.” However, it is not clear if “rough” and “fine” define the process on the basis of (1) the time from the beginning; (2) the molecular weight of products produced at that time; or (3) something else.

Further regarding claims 3 and 14: The claim recites “a tubular reactor *with mixing elements.*” (emphasis added) This limitation appears to conflict with the main claim which appears to preclude mechanical mixing in the hydrolysis process. This apparent discrepancy renders the claim vague and indefinite.

Regarding claim 4: The claim recites “the tubular reactors,” but there is insufficient antecedent basis for this limitation.

Further regarding claims 4, 15, and 16: As noted above, it is not clearly stated exactly what is to be converted, there is insufficient antecedent basis for the limitation “the product to be hydrolyzed.” This appears to be referring to “starch” or “substituted starch” in line 4 of claim 1.

Regarding claim 5: The claim recites “the tubular reactors,” but there is insufficient antecedent basis for this limitation.

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Regarding claims 6 and 20: The terms “the main hydrolysis” and “the tubular tempered reactor.” (line 2) There is insufficient antecedent basis for these limitations.

Further regarding claims 6 and 20: The claims recite that the hydrolysis is “. . . carried out . . . for up to 60-90%.” It is not clear to what this percentage is referring. It is not clear if this means (1) 60-90% of the starch chains have undergone some degree of hydrolysis; (2) the starch is 60-90% depolymerized; (3) the original molecular weight is decreased by 60-90%; (4) the molecular weight is 60-90% of the original molecular weight; or (5) something else. There is an example presented in the specification, where the molecular weight is reduced from 1.4 million D to 300 kD, which would support (3), but this is not clear.

Regarding claim 7: The phrase “preferably” renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 8: The claim recites “reactors provided *with static mixing elements.*” (line 2, emphasis added) This limitation appears to conflict with the main claim which appears to preclude mechanical mixing. This apparent discrepancy renders the claim vague and indefinite.

Regarding claim 9: The term “main hydrolysis” lacks sufficient antecedent basis in the claim.

Further regarding claim 9: The claim recites a hydroxyethylation process and a hydrolysis process. It is not clear if the “partially broken down starch” is a starch hydrolyzate that is hydroxyethylated and then subjected to the process of claim 1 or if it (the hydrolyzate) is a

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product of the process of claim 1 which is then hydroxyethylated. The specification does not clarify this as the single example describes high molecular weight starch that is hydroxyethylated and then subjection to hydrolysis.

Claim 10 provides for the use of starch hydrolyzates, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding claim 11: The claim recites “a pump arrangement.” (line 4) It is not clear if this is simply a pump, as described at page 9, first full paragraph or a pump with some other limitation(s).

Further regarding claim 11: The claim recites “a conduit that connects all units with one another as well as a neutralization station.” It is not clear if the conduit is connected to all the forgoing elements - that is, every component is connected to every other component, or if it is just the “at least one reactor” that are connected in sequence. It is further unclear if “as well as a neutralization station” simply means the addition of that component, or if it is also connected to the other elements by the conduit.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over SOMMERMEYER et al (US 5,218,108) in combination with KOMAI et al (US 3,446,664).

The claims are drawn to a process for the continuous production of starch hydrolyzates wherein the solution to be hydrolyzed is conveyed against the force of gravity through a vertically arranged, one or more tubular reactor(s), essentially free of mixing. Dependent claims are drawn to hydroxyethylation of hydrolyzates and further hydrolysis, or "fine hydrolysis," with mixing. Also claimed is an apparatus for the process having the following required components: (1) feeding device for starch solution; (2) container for a hydrolyzing agent; (3) mixing and heating station; (4) pump arrangement; (5) at least one reactor; (6) conduit; and (7) neutralization station. A dependent claim adds (8) tempering unit(s) for the reactor(s).

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SOMMERMEYER teaches the preparation of hydroxyethyl starch comprising the following steps: (See all of col 4-5)

1. Coarse hydrolysis in an aqueous MeOH/1% HCl solution at 30°-50°C.
2. Neutralization with 1N NaOH and cooling to room temperature.
3. Hydroxyethylation of the partially broken down starch with ethylene oxide in 1N NaOH.
4. Fine hydrolysis in an aqueous acidic solution at 40°-70°C.
5. Neutralization with NaOH and cooling.

As noted above, the limitation of the hydrolysis being carried out in the tubular reactor "for up to 60-90%" is vague and indefinite. This limitation, however it is defined, includes 0% to 90% hydrolysis. The reference describes a starch of 20 million D reduced to several million D. See col 3, lines 3-7. This suggests a hydrolysis in the range recited. The reference further teaches the use of the starch hydrolyzates produced as plasma expanders. See col 3, lines 63-68.

SOMMERMEYER does not teach a continuous process or the use of an apparatus described in the claims.

KOMAI teaches an apparatus for continuous acid hydrolysis of starch. See Fig. 1 - the numerals in boldface refer to the components in the figure. The apparatus comprises a (2) container **13**; (3) mixing and heating station **17**; (4) a metering pump **14**; (5) reactors **18, 19**, and **20**; (6) conduits connecting reactors **29, 30**; and (7) neutralization station **22**.

KOMAI teaches conveyance of the hydrolysis reaction mixture through a plurality of vertically arranged tubular reactors against the force of gravity. The reactors have an inlet tube placed at the bottom and an outlet tube at the top. Several flow routes are outlined at col 4, lines

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43-61. Routes 1-3, 5, and 6 exemplify exclusively upward flow through the reactors. The reference teaches that upward flow cancels out temperature drops due to cooling and consequent reduced flow rate near the wall surface. See col 4, lines 15-18.

KOMAI is silent regarding whether or not the reaction is conducted essentially without mixing. However, the reference teaches that it is desirable to maintain uniform flow and minimize turbulence. See col 4, lines 19-29 and col 5, lines 1-3. The reference, if not explicitly teaching hydrolysis "essentially without mixing," clearly teaches away from additional mechanical mixing which would increase turbulence.

KOMAI exemplifies a hydrolysis temperature different from that recited in the claims. However, the reference recognizes that it is known in the art to control the reaction velocity by varying conditions such as reaction temperature.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to conduct the process of SOMMERMEYER continuously using the KOMAI apparatus, comprising conveyance of the reaction mixture against the force of gravity, essentially without mixing, at the temperatures recited. The artisan would be motivated to use this apparatus for its art-disclosed utility with a reasonable expectation of success.

KOMAI does not teach a (1) feeding device for the starch solution. The reference is also silent regarding (8) tempering unit(s) for the reactor(s). The reference describes the process as beginning with a pre-combined solution of starch and acid in container 13.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a (1) feeding device for the starch solution and (8) tempering unit(s) for the reactor(s). At some point before the reaction takes place, the acid and starch must be stored in separate containers. The artisan would be motivated to modify the KOMAI apparatus by adding a feeding device in order to convey the starch from a storage container to container 13. The artisan would be motivated to add tempering unit(s) to the reactor(s) in order to better control the temperature, and therefore the reaction products, at any given point in the process.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to also conduct the hydroxethylation reaction as a continuous process. A continuous process is *prima facie* obvious in light of batch process. In view of the fact that the neutralization step provides a reaction mixture (starch hydrolyzate + 1N NaOH) comprising two-thirds of the required components for the hydroxethylation, the process would be particularly well suited to add this reaction as a continuous process in line with the continuous hydrolysis process. The ordinarily skilled worker would be motivated to add the continuous hydroxyethylation for overall convenience in providing a more compact process with a reasonable expectation of success.

It would be obvious to one having ordinary skill in the art at the time the invention was made to conduct the fine hydrolysis with mixing. It would also be obvious to cool the hydrolysis mixture prior to neutralization in order to compensate for the heat generated in the exothermic

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acid-base neutralization reaction. The artisan would be motivated to mix the reaction mixture in order facilitate the change in the temperature (cooling).

It would be obvious to one having ordinary skill in the art to use the thus produced starch hydrolyzates formed in the process as a plasma expander, for the art-disclosed utility, as per SOMMERMEYER.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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Leigh C. Maier  
Patent Examiner  
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